IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

CONSTANCE SUNDELL, Plaintiff, vs. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	§ § § § § § § § § §	CASE NO.: 8:21-cv-00032

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANT NOVARTIS PHARMACEUTICAL CORPORATION'S MOTION TO DISMISS FIRST AMENDED COMPLAINT

INTRODUCTION

Novartis erroneously contends that Plaintiff's complaint should be dismissed for failure to state a plausible claim for relief.[1] However, as discussed more fully herein, Plaintiff has stated viable claims for strict liability, negligence, fraudulent misrepresentation, and negligent misrepresentation.

Contrary to Novartis' assertions, the product labeling for Beovu has failed at all times to properly warn of retinal vasculitis or retinal vascular occlusion. Novartis at all times had the ability and duty to ensure its product labeling did adequately warn of these risks. Moreover, Plaintiff's state law claims premised on this failure are not preempted because they are based on inaccurate, incomplete, and, in some cases, fraudulent information provided to Plaintiff and her treating physicians. Plaintiff has also pleaded a viable negligence-based claim related to Novartis' failure to properly test Beovu. Likewise, Plaintiff's claim for fraudulent misrepresentation has been pleaded with sufficient particularity to satisfy the requirements of Federal Rule of Civil Procedure 9(b).

BACKGROUND

Beovu became available for use in the United States in October 2019.[2] Beovu is indicated to treat wet age-related macular degeneration and is the third product to receive approval to treat that condition in the United States.[3] Unlike the previously approved treatments, Beovu causes a very severe set of eye injuries which are referred to as retinal vasculitis or retinal vascular

[1] Def's Mem. at 1.

[2] Filing No. 30 ¶ 23.

[3] *Id.* ¶ 26.

occlusion. Retinal vasculitis is characterized by inflammation of the vessels of the retina typically leading to a decrease in vision.[4] Retinal vasculitis can lead to retinal vascular occlusion and/or retinal artery occlusion.[5] Retinal vascular occlusion is characterized by an obstruction of the venous or arterial system of the retina, usually by a thrombus or embolus, causing vision loss which can be severe and permanent.[6] If the occlusion occurs in the veins of the retina, the occlusion is referred to as a retinal vein occlusion.[7] If the occlusion occurs in the arteries of the retina, the occlusion is referred to as a retinal artery occlusion.[8]

Beovu's propensity to cause these injuries was apparent from Novartis' phase 3 clinical trials, however, Novartis failed to properly disclose this information to patients and physicians.[9] Moreover, following the introduction of the product for public use, additional reports began to surface which further put Novartis on notice of Beovu's relationship to these severe eye injuries.[10] Despite possessing this information, Novartis failed to update its product labeling to warn about the risk of retinal vasculitis and retinal vascular occlusion until June 2020.[11] The

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[4] *Id.* ¶ 32.

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.* Herein the term "retinal vascular occlusion" is used to refer to occlusions of either the arteries or the veins in the retina.

[9] Filing No. 30 ¶¶ 90, 91.

[10] *Id.* ¶¶ 70-76.

[11] *Id.* ¶¶ 38, 40.

updated warning on retinal vasculitis and retinal vascular occlusion was prompted by post-marketing adverse event reports of the conditions received by Novartis.[12] [13] However, even to this day, the product labeling for Beovu continues to fail to properly warn of the risk of these conditions related to Beovu use.[14]

Plaintiff was prescribed and injected with Beovu on January 21, 2020 and January 30, 2020.[15] Thereafter, she suffered severe vision loss.[16] The vision loss resulted from retinal vascular occlusion related to her use of Beovu.[17] As noted above, at all times prior to her use of Beovu, and prior to her diagnosis with retinal vascular occlusion, Novartis failed to properly warn her treating physician of Beovu's propensity to cause the very injury Plaintiff suffered despite possessing a wealth of information which supported the dissemination of such a warning well before Plaintiff's use of the drug.

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[12] Plaintiff agrees with Novartis that it is appropriate for the Court to take judicial notice of certain publicly available documents and request that the Court do so here. Plaintiff is including several such documents as part of a separately filed Exhibit Index to this brief. These documents appear as exhibits "A-D" in the Exhibit Index.

[13] *See* June 11, 2020 Novartis Press Release; https://www.novartis.com/news/media-releases/us-fda-approves-updated-novartis-beovu-label-include-additional-safety-information; Attached as Ex. "A" to Exhibit Index.

[14] Filing No. 30 ¶¶ 119, 120(a).

[15] *Id.* ¶ 13.

[16] *Id.*

[17] *Id.*

Plaintiff filed her initial Complaint on January 27, 2021. Plaintiff filed a First Amended Complaint on March 30, 2021.[18]

ARGUMENT

I. LEGAL STANDARD

In order "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[19] The complaint need not contain detailed factual allegations, but it must provide more than "a formulaic recitation of the elements of a cause of action."[20] Under Rule 8(a), the plaintiff must "give the defendant fair notice of what the ... claim is and the grounds upon which it rests."[21] In reviewing a complaint in the context of a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the court must "accept as true all facts pleaded by the non-moving party and grant all reasonable inferences from the pleadings in favor of the non-moving party."[22]

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[18] Filing No. 30.

[19] *Ashcroft v. Iqbal,* 556 U.S. 662 (2009) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544 (2007)).

[20] *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555 (2007).

[21] *Id.* at 555 (internal citation and quotation marks omitted).

[22] *United States v. Any & All Radio Station Transmission Equip.,* 207 F.3d 458, 462 (8th Cir.2000).

II. PLAINTIFF HAS STATED PLAUSIBLE AND VIABLE CLAIMS FOR RELIEF.

a. Plaintiff has offered ample evidence demonstrating that the Beovu product labeling was not adequate as a matter of law.

Novartis incorrectly claims that its labeling for Beovu has at all times adequately warned about retinal vasculitis and retinal vascular occlusion.[23]

Under Nebraska law, a manufacturer is "subject to liability for failing either to warn or adequately to warn about a risk or hazard inherent in the way a product is designed that is related to the intended uses as well as the reasonably foreseeable uses that may be made of the product it sells."[24] A warning is only "adequate if it accurately and unambiguously conveys the scope and nature of the risk to the prescribing physician."[25] Further, even "facially accurate statements of fact regarding a particular risk are not adequate as a matter of law where there are disputes over whether the warning was sufficiently explicit and detailed."[26] Importantly, warning adequacy is not appropriate to consider solely based on the pleadings because "in the prescription drug arena, expert medical testimony is needed to determine whether the drug manufacturer's warning to the medical community is adequate."[27]

As Plaintiff's First Amended Complaint (hereinafter "FAC") alleges and demonstrates, prior to June 2020 the product labeling for Beovu failed to include a warning about the risk of

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[23] Def's Mem. at 10.

[24] *Freeman v. Hoffman-La Roche*, 618 N.W.2d 827, 841 (Neb. 2000).

[25] *Ideus v. Teva Pharmaceuticals U.S.A, Inc.,* 361 F.Supp.3d 938, 946 (D. Neb. 2019).

[26] *Vallejo v. Amgen, Inc.,* 2014 WL 4922901, *3 (D. Neb. Sep. 29, 2014).

[27] *Ideus,* 361 F.Supp.3d at 946-947 (citing to *Scelta v. Boehringer Ingelheim Pharmaceuticals, Inc.,* 404 F.App'x. 92, 94 (8th Cir. 2010).

retinal vasculitis or retinal vascular occlusion with Beovu use.[28] Given that Plaintiff's use of the drug predated this new warning by approximately six months, it cannot be reasonably argued that Novartis warned Plaintiff's prescribing physician about the risk of retinal vascular occlusion and retinal vasculitis prior to Plaintiff's use of the drug.[29] Plaintiff's FAC further demonstrates that the danger associated with retinal vasculitis and retinal vascular occlusion is substantial and was a danger Novartis was on notice of from its own clinical trial data for Beovu and from post-marketing adverse event reports.[30]

Despite these facts, Novartis argues that a chart contained in the "Clinical Trials Experience" subsection of the "Adverse Reactions" section of the label, which merely indicates that 1% of Beovu users experienced retinal artery occlusion in the clinical trials for the drug constitutes a warning about retinal vasculitis and retinal vascular occlusion that is adequate as a matter of law.[31] As Plaintiff demonstrates in her FAC, even this information has at all times falsely and incompletely conveyed the risk of retinal vasculitis and retinal vascular occlusion from the Beovu clinical trials. In fact, these events actually occurred in at least 3.3% of Beovu trial patients, rather than in 1% of those patients as Novartis has stated in the product labeling for Beovu.[32] Additionally, the product labeling for Beovu has, at all times, failed to warn that there was an approximately 2,312% relative increased risk of retinal vasculitis and retinal vascular

[28] Filing No. 30 ¶¶ 38, 40.

[29] *Id.* ¶ 13.

[30] *Id.* ¶¶ 31, 32, 70-75, 110-113, 117.

[31] Def's Mem. at 11.

[32] Filing No. 30 ¶¶ 90, 119, 120(a).

occlusion in Beovu users in the clinical trials as compared to users of the control drug aflibercept.[33]

Novartis also argues that language in the product labeling about eye injuries unrelated to retinal vasculitis or retinal vascular occlusion constitutes a warning that is adequate as a matter of law as to retinal vasculitis and retinal vascular occlusion.[34] First, from a common sense perspective, it is counterintuitive that language in the product labeling concerning unrelated eye injuries serves to adequately warn Plaintiff's prescribing physician about the injury she suffered – retinal vascular occlusion. Second, as discussed in more detail below, none of the cases cited by Novartis support this proposition either.

The two cases cited by Novartis that apply Nebraska law in assessing adequacy of warnings further support the conclusion that a finding of warning adequacy as a matter of law is inappropriate here. The first case cited by Novartis for this proposition is *Ideus v. Teva Pharmaceuticals, USA, Inc.,* 361 F.Supp.3d 938 (D. Neb. 2019).

At the outset, *Ideus* involved an assessment of warnings adequacy as part of a summary judgment motion after both parties had completed discovery and were permitted to offer expert reports on warnings adequacy.[35] Further, in *Ideus,* the Plaintiff offered no expert testimony supporting her position that the warning for the product at issue was inadequate.[36] The Court further recognized that "in the prescription drug arena, expert medical testimony is needed to

[33] *Id.* ¶¶ 91, 119, 120(a).

[34] Def's Mem. at 10-11.

[35] *Ideus,* 361 F.Supp.3d at 940, 947.

[36] *Ideus* at 947.

determine whether the drug manufacturer's warning to the medical community is adequate."[37] The Defendant's summary judgment motion was ultimately granted because a specific and unambiguous warning was present as to the exact injury suffered by Plaintiff paired with the fact that Defendant offered expert testimony demonstrating the adequacy of that label, which was unrebutted by any expert testimony by Plaintiff.[38]

The second case cited by Novartis to support its warnings adequacy argument is *Vallejo v. Amgen, Inc.,* 2014 WL 4922901 (D. Neb. Sept. 29, 2014). *Vallejo* involved a motion to dismiss, rather than a motion for summary judgment. However, the Court in *Vallejo* ultimately concluded that it could not find the warning at issue "adequate as matter of law" given the parties dispute as to whether the existing labeling properly warned of the injury in question especially given the need for expert testimony on warnings adequacy in a prescription drug case.[39]

A review of *Ideus* and *Vallejo* clearly demonstrates that dismissal on the basis of warnings adequacy is inappropriate in this case. Here, in stark contrast to both *Ideus* and *Vallejo,* the product labeling for Beovu included no warning at all about retinal vascular occlusion or retinal vasculitis prior to Plaintiff's use of Beovu and subsequent diagnosis with retinal vascular occlusion.[40] As noted above, the only information that did relate to retinal vascular occlusion in the product labeling for Beovu was false, misleading, and woefully

[37] *Ideus* at 946-947.

[38] *Id.*

[39] *Vallejo,* 2014 WL 4922901 at *3-4.

[40] Filing No. 30 ¶¶ 38, 40.

incomplete.[41] Further, given the need for expert testimony to assess warnings adequacy, as noted by both *Ideus* and *Vallejo,* it would be wholly improper to consider Novartis' motion to dismiss solely on the pleadings and without providing Plaintiff with the opportunity to engage in discovery and offer expert opinions on the inadequacy of the Beovu product labeling. In short, Plaintiff's FAC certainly creates a fact question as to the adequacy of Beovu's product labeling as it relates to retinal vasculitis and retinal vascular occlusion, which cannot properly be adjudicated on the pleadings alone.

b. Plaintiff has pleaded viable claims regarding the initial labeling for Beovu that are not preempted.

As the manufacturer of Beovu, Novartis is charged with being responsible for the "content of its label *at all times*."[42] FDA regulations specifically provide that a drug manufacturer, not the FDA, "is charged both with *crafting an adequate label* and with ensuring that its warnings remain adequate as long as the drug is on the market."[43]

Plaintiff's FAC includes numerous allegations demonstrating that the Beovu product labeling was inadequate at all times pertinent to this case, including at the time the product was launched. As noted above, the labeling for Beovu has at all times failed to provide accurate

[41] *Id.* ¶¶ 90, 91, 118-120.

[42] *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009) (emphasis added).

[43] *Id.* at 570-71 (emphasis added). *See also Guidry v. Janssen Pharmaceuticals, Inc.,* 206 F.Supp.3d 1187, 1209 (E.D. La. 2016) (concluding that claims based on need for manufacturer to cure defect in product prior to seeking FDA approval is not preempted); *Holley v. Gilead Sciences, Inc.,* 379 F.Supp.3d 809, 826 (N.D. Cal. 2019) (finding that plaintiffs' claims were not preempted "to the extent that Plaintiffs contend that Gilead should have submitted different warnings as part of their initial submissions for FDA approval"); *In re Actos Products Liability Litigation,* 2014 WL 60298, *7 (W.D. La. Jan 7, 2014) (finding that drug manufacturer had ability to submit stronger warning language to FDA both prior to and after drug approval).

information concerning the incidence of retinal vascular occlusion and retinal vasculitis in the Beovu clinical trials.[44] Additionally, the product labeling for Beovu has at all times also failed to include information concerning the relative risk of retinal vasculitis and retinal vascular occlusion from the clinical trials for Beovu when comparing Beovu users to users of the active control drug.[45] Additionally, no warning related to Beovu and retinal vasculitis or retinal vascular occlusion was included in the product labeling for Beovu until after Plaintiff's use of Beovu and subsequent diagnosis with retinal vascular occlusion.[46]

Given the clinical trial data demonstrating that at least 36 patients in the clinical trials for Beovu experienced retinal vasculitis and/or retinal vascular occlusion, there was ample information to warrant a warning on retinal vasculitis and retinal vascular occlusion at the time the product was launched.[47] The fact that this number of adverse events was not uncovered publicly until after Plaintiff's injury is immaterial because this information was in Novartis' possession at all times prior to Plaintiff's use of Beovu.[48] Novartis was certainly obligated when the drug was launched to include this information accurately in the product labeling for Beovu, which it completely failed to do.

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[44] Filing No. 30 ¶¶ 90, 118-120.

[45] *Id.* ¶¶ 91, 118-120.

[46] *Id.* ¶¶ 13, 38, 40.

[47] *Id.* ¶ 111.

[48] *Id.* ¶ 110.

c. Newly acquired information also existed, which necessitated that a warning be added regarding retinal vasculitis and retinal vascular occlusion prior to Plaintiff's use of Beovu.

Despite Novartis' contention to the contrary, sufficient newly acquired information existed to support the inclusion of a warning about retinal vasculitis and retinal vascular occlusion prior to Plaintiff's use of the drug. Once a drug is placed on the market, a manufacturer must update its product labeling based on "newly acquired information", which is not limited to new data, but also encompasses "new analyses of previously submitted data."[49] This "rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments. . . ."[50] In short, "if a manufacturer submits adverse event data to the FDA, then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, this meets the requirement for newly acquired information."[51]

As this Court has previously found, "when considering a preemption argument in the context of a motion to dismiss, the factual allegations relevant to preemption must be viewed in the light most favorable to the plaintiff."[52] This Court further held that to survive a motion to dismiss based on a lack of newly acquired information, Plaintiff need only provide "some indication of newly acquired information as to trigger the applicability of the CBE regulation."[53]

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[49] *See Wyeth,* 555 U.S. at 568 (citing 73 Fed. Reg. 49604).

[50] *Id.*

[51] *In re Taxotere (Docetaxal) Products Liability Litigation*, 2020 WL 7480623, *9 (E.D. La. Dec. 18, 2020) (citing *Wyeth v. Levine,* 555 U.S. at 569).

[52] *Ideus v. Teva Pharmaceuticals USA, Inc.*, 2017 WL 6389630, *2 (D. Neb. Dec. 12, 2017) (internal quotations omitted).

[53] *Id.*

Similarly, it is inappropriate for the Court at this stage to engage in weighing the newly acquired evidence Plaintiff has offered from a causation perspective.[54]

Plaintiff has pleaded substantial allegations demonstrating that newly acquired information existed before she was diagnosed with retinal vascular occlusion, which warranted the addition of a warning about retinal vasculitis and retinal vascular occlusion. As Plaintiff has alleged, eight patients suffered retinal vasculitis or retinal vascular occlusion that were reported to the company in the post-marketing setting prior to Plaintiff's final dose of Beovu.[55] One of these adverse event reports alone was sufficient, at a minimum, to re-analyze all reports of retinal vasculitis or retinal vascular occlusion the company had received in the clinical trials and in the post-marketing setting. Additionally, the combination of these adverse event reports in conjunction with the existing reports of retinal vasculitis and retinal vascular occlusion from the Beovu clinical trials was more than sufficient to warrant the addition of a warning to the Beovu product labeling prior to Plaintiff's use of Beovu.[56]

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[54] *See e.g., In Re Testosterone Replacement Therapy Products Liability Litigation*, 2014 WL 7365872, *3 (N.D. Ill. Dec. 13, 2014) (in assessing a motion to dismiss related to lack of causation the court concluded "it is inappropriate to assess the weight of the evidence at the motion to dismiss stage. The plausibility requirement demands only that a plaintiff provide sufficient detail to present a story that holds together.") (internal citations and quotations omitted).

[55] Filing No. 30 ¶¶ 13, 70-74. These eight patients suffered twelve unique diagnosed injuries as documented in the reports themselves.

[56] Even if Novartis contends it was not aware of the thirty-three reports of retinal vasculitis or retinal vascular occlusion from its clinical trials, one adverse event report regarding these conditions in the post-marketing setting constituted new evidence that warranted a complete re-review of the clinical trial data by Novartis, which would have readily revealed these additional reports from the clinical trials.

But, Novartis takes the perplexing position that these adverse event reports are insufficient to demonstrate newly acquired information which would warrant action by the company.[57] However, this contention overlooks several vital facts.

First, Novartis conveniently omits that the very label change the company instituted only four months after Plaintiff's last dose of Beovu was premised on the very same adverse event reports Plaintiff presents as newly acquired information supporting a label change. [58] It simply defies logic to contend that the very reports used to support the label change almost immediately after Plaintiff's use of the drug does not support the finding of newly acquired information which would have triggered the necessity of a label change in the first instance.

Second, Novartis' general characterization of adverse event reports is plainly inaccurate. Novartis argues that adverse events alone without any causality analysis cannot be considered newly acquired information to trigger a label change.[59] This view, however, overlooks the FDA's own stance on this point. FDA has plainly stated that adverse event reports like those relied on by Plaintiff here are imbued with "implied causality".[60] Thus, especially at the motion

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[57] Def's Mem. at 15-18.

[58] *See* June 11, 2020 Novartis Press Release ("Novartis announced today that the US Food and Drug Administration (FDA) has approved a label update for Beovu® (brolucizumab) to include additional safety information regarding retinal vasculitis and retinal vascular occlusion. This approval follows Novartis' announcement that it would pursue worldwide label updates after a review and further characterization of rare post-marketing safety events reported to Novartis."); https://www.novartis.com/news/media-releases/us-fda-approves-updated-novartis-beovu-label-include-additional-safety-information; Attached as Ex. "A" to Exhibit Index.

[59] Def's Mem. at 15-18.

[60] Guideline for Industry, Clinical Safety Data Management: Definitions and Standards for Expedited Reporting, Food and Drug Administration (1995), p. 10; https://www.fda.gov/media/71188/download; Attached as Ex. "B" to Exhibit Index.

to dismiss phase where Plaintiff has yet to engage in discovery, the Court should view the relevant adverse event reports which pre-date Plaintiff's exposure to Beovu as being causally related to the drug unless or until that position is disproven by Novartis.

Third, Novartis improperly minimizes the quality of the adverse event reports in question here. The majority of the adverse event reports received by Novartis prior to Plaintiff's last exposure to Beovu came from treating physicians who simply do not make adverse event reports to the company unless they believe the drug caused the event in question.[61] Thus, Novartis' contention that these reports were not of sufficient quality to warrant a label change is belied by the nature of the reports themselves.

Fourth, Novartis fails to acknowledge that these adverse event reports were not the only relevant information available to the company prior to Plaintiff's use of Beovu that constituted newly acquired information. As previously noted, newly acquired information "consists of data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) … new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type of greater severity or frequency than previously included in submissions to the FDA."[62] Here, Novartis had at least thirty-three cases of retinal vasculitis or retinal vascular occlusion from its clinical trials which were not reported to FDA as part of the agency's review of the Beovu clinical trial data.[63] All thirty-three of these

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[61] *See* FDA Beovu Adverse Event Data for Retinal Vasculitis and Retinal Vascular Occlusion Events Reported to FDA up to January 30, 2020. Attached as Ex. "C" to Exhibit Index.

[62] 21 C.F.R. § 601.12 (f)(6).

[63] Filing No. 30 ¶¶ 111, 113, 117; Food and Drug Administration, Center for Drug Evaluation and Research Summary Review, p. 31; Attached as Ex. "D" to Exhibit Index; *See also Reference Manual on Scientific Evidence* , p. 723 (Third Edition, 2011) (recognizing randomized clinical

cases were deemed to be either definitely or probably caused by Beovu.[64] Importantly, this review was based solely on information that was available to Novartis well prior to Plaintiff's use of Beovu. Thus, the Court does not even need to determine whether the adverse event reports alone are enough to constitute newly acquired information given the presence of these additional reports, which clearly have causal attribution associated with them.

Fifth, Novartis mischaracterizes the level of evidence required to constitute newly acquired information. Novartis discusses the aspect of the regulations that require "reasonable evidence of a causal association" in order to add information to the "Warnings and Precautions" section of the product label, but fails to include a complete definition of that concept and fails to acknowledge that the standard is much lower to add information to other portions of the product labeling.[65] In discussing the level of evidence needed to constitute "reasonable evidence of a casual association" the regulations further state that "a causal relationship need not have been definitely established." [66]

Moreover, information concerning retinal vasculitis and retinal vascular occlusion should have and could have been added to the "Adverse Reactions" section of the product labeling for Beovu solely based on adverse effects that are "reasonably associated with the use of a drug".[67]

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trials as the second strongest form of medical evidence on the hierarchy of medical evidence) (internal citations omitted).

[64] Filing No. 30 ¶ 117; Mones et al., *Risk of Inflammation, Retinal Vasculitis and Retinal Occlusion-Related Events with Brolucizumab: Post-Hoc Review of HAWK and HARRIER,* American Academy of Ophthalmology (Nov. 2020).

[65] Def's Mem. at 16.

[66] 21 C.F.R. § 201.57(c)(6)(i).

[67] 21 C.F.R. § 201.57(c)(7).

This distinction is vitally important because none of the cases cited by Novartis which address the concept of newly acquired information do so in the context of the addition of information into the "Adverse Reactions" section of the product labeling. Thus, Novartis has offered no evidence demonstrating that this lesser standard was not met by way of the adverse event reports and non-disclosed clinical trial data, which was all available prior to Plaintiff's exposure to Beovu.

Finally, Novartis specifically discusses two cases from other jurisdictions that it contends support its view that newly acquired information has not been adequately pleaded by Plaintiff here. Both of those cases are readily distinguishable from this case. Novartis first points to *Mahnke v. Bayer Corp.,* 2019 WL 8621437, (C.D. Cal. Dec. 10, 2019). The court in *Mahnke* concluded that plaintiff failed to meet its burden of pleading newly acquired information because the plaintiff pointed to no newly acquired information that existed prior to her exposure to the drug in question.[68]

Novartis also discusses *Sabol v. Bayer Healthcare Pharm. Inc.,* 439 F.Supp.3d 131 (S.D.N.Y. 2020) to support its view that Plaintiff has not offered newly acquired information here. The court in *Sabol* found that newly acquired information was not present based almost entirely on the fact that the plaintiff was unable to offer any evidence of an actual injury or adverse effect that was related to the drug in question.[69] In fact, the court found that Plaintiff had

[68] *Mahnke,* 2019 WL 8621437 at *4 ("Plaintiff focuses only on one piece of 'newly acquired information' which purportedly warranted use of the CBE regulation."' But this information "was published outside of the relevant time frame. Accordingly, it is insufficient to show that Bayer could have invoked the CBE regulation.").

[69] *Sabol,* 439 F.Supp.3d at 147.

merely offered evidence that the drug in question (gadolinium) is retained in the body after use, which the FDA had expressly stated was not found to be linked with any actual adverse effect to the patient.[70]

The instant facts vary dramatically from those in *Mahnke* and *Sabol*. Here, Plaintiff has pointed to multiple pieces of newly acquired information before her use of Beovu by way of the adverse event reports – some of which clearly demonstrated a causal relationship between Beovu and retinal vasculitis or retinal vascular occlusion – and thirty-three cases of retinal vasculitis or retinal vascular occlusion from the Beovu clinical trials which were found to be related to Beovu use and were not shared with the FDA prior to Plaintiff's use of Beovu. There can also be no question that in this regard Beovu was shown to be linked to severe injuries prior to Plaintiff's use of the drug.

For similar reasons, the additional cases cited by Novartis in footnote 73 of its brief are equally unavailing.[71] *Gayle v. Pfizer,* 2020 WL 1685313 (S.D.N.Y. April 7, 2020) does reach the flawed conclusion that adverse event reports that lack causality statements are not sufficient to constitute newly acquired information.[72] However, this is an outlier opinion that has not been followed by numerous other courts that have addressed the issue.[73] This opinion also comes

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[70] *Id.*

[71] Def's Mem. at 17, fn. 73.

[72] *Gayle v. Pfizer,* 452 F.Supp.3d at 88.

[73] *See e.g., Mitchell v. Boehringer Ingelheim Pharmacueticals, Inc.,* 2017 WL 561473, *6 (W.D. Tenn. Nov. 21, 2017) (concluding that adverse event reports without causality assessments were sufficient to constitute newly acquired information and argument about the quality and nature of those reports is "more appropriately made in a motion for summary judgment after discovery"); *Newman v. McNeil Consumer Healthcare,* 2012 WL 39793, *10 (N.D. Ill. Jan. 9, 2012) (finding that adverse event reports do constitute newly acquired information even without causality

from a court outside of the Eighth Circuit and the decision is currently on appeal. Additionally, its conclusion has no application here because Plaintiff has offered newly acquired information that does include findings of causation both from the adverse event reports and the clinical trial cases that were not reported to FDA.[74] Finally, this case is easily distinguished from the instant case because, as noted above, the label change made by Novartis was made very shortly after Plaintiff's use of Beovu and was based, by Novartis' own admission, on adverse event reports.

d. Novartis has not offered clear evidence that the FDA would have rejected adequate labeling information on retinal vasculitis and retinal vascular occlusion at any point in time.

Plaintiff has offered ample evidence supporting that a warning on retinal vasculitis and retinal vascular occlusion should have been included in the initial product labeling for Beovu and that certainly newly acquired information existed supporting that change prior to Plaintiff's use of the drug. The burden now shifts to Novartis to bring forward clear evidence that the FDA would have rejected these label changes.

In this context, Novartis bears a heavy burden when arguing that federal requirements made it impossible to strengthen its label. Novartis must come forward with "clear evidence" that if it had updated its label pursuant to its duties under state tort law, the FDA would have

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assessments in the reports because "it is plain that the FDA has made the decision to rely on them and utilize them in its determinations" and these reports need not establish causation in order to constitute newly acquired information); *Blackburn v. Shire US, Inc.,* 2017 WL 1833524, *4 (N.D. Ala. May 8, 2017) (holding that adverse event reports can constitute newly acquired information).

[74] The remaining cases cited by Novartis in footnote 73 involve *Daubert* challenges where courts found that standing along adverse event reports cannot definitely establish causation. These opinions have no bearing on whether Plaintiff has sufficiently pled her causes of action here, which are based only in part on adverse event reports.

intervened and rejected the label change.[75] In this context, '"clear evidence' is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning."[76] Thus, the Court can only grant dismissal on the basis of preemption where, resolving all questions of fact in Plaintiff's favor, the administrative record clearly shows the FDA would not have allowed the label change after being fully informed about the information supporting the proposed change.

Here, as previously discussed, FDA was not fully informed about the true frequency of retinal vasculitis and retinal vascular occlusion cases in the Beovu clinical trials. Moreover, FDA permitted the addition of warning language in June 2020 concerning retinal vasculitis and retinal vascular occlusion based solely on adverse event reports. Thus, it cannot reasonably be argued that clear evidence exists showing that FDA would have rejected a proper warning on retinal vasculitis and retinal vascular occlusion either in the pre-marketing phase or in the post-marketing phase prior to Plaintiff's use of Beovu.

f. Plaintiff's claims are likewise not preempted under *Buckman*.

Novartis also erroneously contends that Plaintiff's claims are preempted under *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001).[77] Quite simply, the reasoning in *Buckman* is inapplicable to Plaintiff's claims for multiple reasons.

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[75] *See Wyeth*, 555 U.S. at 571.

[76] *Merck Sharp & Dohme Corp. v. Albrecht,* 139 S.Ct. 1668, 1672 (2019).

[77] Def's Mem. at 8-10.

First, *Buckman* involved the interpretation of state law claims brought by a plaintiff and their intersection with the Medical Device Amendments (hereinafter "MDA") to the Food, Drug, and Cosmetic Act.[78] The plaintiff's state law claims were premised entirely on plaintiff's assertion that the defendant made fraudulent misrepresentations to FDA in the course of obtaining approval for its medical device.[79] In finding plaintiff's claims preempted, the court relied heavily on the Congressional intent associated with the establishment of the MDA. The Court concluded that in enacting the MDA Congress intended for FDA itself to retain the power to "punish and deter fraud" against it and that Congress intended that right as it pertained to the MDA to "be enforced exclusively by the Federal Government."[80] Additionally, the Court concluded that since "policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' such as to warrant a presumption against finding federal pre-emption of a state-law cause of action."[81] Ultimately, given that plaintiff's claims did not rely on "traditional state tort law" and would frustrate Congress' intent in enacting the MDA a finding of preemption was warranted.[82]

Here, unlike *Buckman,* Plaintiff's claims do not arise from the MDA at all and instead flow from traditional state-law tort causes of action. Under these circumstances the strong

[78] *Buckman,* 531 U.S. at 343.

[79] *Id.*

[80] *Id.* at 348, 352.

[81] *Id.* at 347.

[82] *Id.* at 353.

presumption against preemption applies.[83] In fact, courts have consistently concluded that state-law tort claims, like those brought by Plaintiff, are not preempted under the theory at issue in *Buckman*.[84] Ultimately, to the extent Plaintiff relies on any representations made to the FDA it is to demonstrate the presence of newly acquired information to defeat Novartis' preemption defense, rather than as affirmative evidence to prove her claims.

The conclusion that *Buckman* is inapplicable to Plaintiff's instant claims is further supported by Novartis' own argument in support of preemption. In fact, the very cases cited by Novartis support the inapplicability of *Buckman* here. For example, the only case cited by Novartis arising from the 8th Circuit to support its contention that *Buckman* preemption applies to Plaintiff's case – *Lefaivre* – actually reached the opposite conclusion. In analyzing state law product liability claims similar to those brought by Plaintiff here, the Court in *Lefaivre* found that "the present case is distinguishable from *Buckman* because Lefaivre's state-law claims are not

[83] *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct.at 1677 (interpreting the FDCA's provisions related to state-law tort claims and concluding that Congress' intent was clear in providing no federal remedy for violation of the FDCA and instead demonstrating an intent to permit state-law tort claims to proceed in order to protect consumer health and safety); *See also Lefaivre v. KV Pharmaceutical Co.,* 636 F.3d 935, 944 (8th Cir. 2011) ("Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (quoting *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.,* 621 F.3d 781, 792 (8th Cir. 2010).

[84] *See e.g., Stengel v. Medtronic,* 704 F.3d 1224, 1233 (9th Cir. 2013) (concluding that state-law failure-to-warn claims were claims independent of federal regulations that otherwise paralleled federal duties and thus were not preempted under *Buckman*); *In re Actos Products Liability Litigation,* 2014 WL 60298 at *8 (finding *Buckman* inapplicable to state-law tort claims that were not predicated on a showing of fraud on the FDA); *Saavedra v. Eli Lilly and Co.,* 2013 WL 6345442, *7 (C.D. Cal. Feb. 26, 2013) (citing *Wyeth v. Levine* in support of its conclusion that traditional state-law tort claims are not preempted by *Buckman* just because of FDA's involvement with the drug).

fraud-on-the-FDA claims as they focus on harm that is allegedly perpetrated against consumers rather than the FDA."[85]

Moreover, Novartis points to only a few paragraphs in Plaintiff's Complaint to support its flawed position that Plaintiff has brought fraud on the FDA type claims.[86] However, each of these paragraphs actually addresses fraudulent statements and omissions directed at Plaintiff and/or her prescribing physician, not the FDA. To the extent Novartis attempts to present an argument to the contrary, that position is belied by the plain language of the allegations themselves.

Based on the foregoing, it is readily apparent that Plaintiff's claims are traditional state-law claims that are not implicated in any form or fashion by the Court's ruling in *Buckman*. As such, these claims are clearly not preempted according to any principles flowing from *Buckman*.

IV. PLAINTIFF HAS ALSO ADEQUATELY PLEADED A CAUSE OF ACTION RELATED TO NOVARTIS' NEGLIGENT FAILURE TO TEST BEOVU.

Novartis improperly characterizes the entirety of Plaintiff's claims as being premised on failure to warn theories.[87] In fact, Plaintiff's negligence count includes a claim related to Novartis' negligent failure to test Beovu.[88] As pleaded by Plaintiff, this count relates to Novartis' failure to properly account for the number of retinal vasculitis and retinal vascular occlusion cases in its clinical trials for Beovu.[89] These allegations also include Novartis' failure

[85] *Lefaivre,* 636 F.3d at 944 (internal citations and quotations omitted).

[86] Def's Mem. at 9-10, fns. 37-40.

[87] Def's Mem. at 1-2.

[88] *See* Filing No. 30 ¶¶ 95, 97, 98(h), 98(k).

[89] *Id.* ¶ 98(h).

to properly study the drug in the primary group of patients that were taking it – those that were switching from another anti-VEGF agent to Beovu.[90]

Novartis makes no attempt to argue these allegations are improperly pleaded. Negligent failure to test claims – such as the one made by Plaintiff here – are also supported by Nebraska law.[91] Thus, Plaintiff's negligence claim, which is partially premised on a negligent failure to test, should also survive Novartis' dismissal attempt.

V. PLAINTIFF HAS PLEADED HER FRAUDULENT MISREPRESENTATION CLAIM WITH SUFFICIENT PARTICULARITY.

Novartis incorrectly contends that Plaintiff has not pleaded her fraud claim with sufficient particularity.[92] Federal Rule of Civil procedure 9(b) requires that "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally."

In the Eighth Circuit, to satisfy this particularity requirement a claim should "identify the who, what, where, when, and how" of the fraud.[93] "Although conclusory allegations that a defendant's conduct was fraudulent and deceptive are not enough to satisfy Rule 9(b), it is sufficient for a claimant to set forth the time, place, and circumstances of the alleged fraudulent activities."[94] The test of pleading under Rule 9(b) is whether the pleading gives fair notice of the

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[90] *Id.* ¶ 98(k).

[91] *See generally Freeman v. Hoffman-La Roche, Inc.,* 260 Neb. 552 at 569-571.

[92] Def's Mem. at 20.

[93] *U.S. ex rel. Costner v. U.S.,* 317 F.3d 883, 888 (8th Cir. 2003).

[94] *Gilmer v. Buena Vista Home Video, Inc.,* 939 F.Supp. 665, 672 (W.D. Ark. 1996).

claims asserted and the basic transactions upon which the claims are based."[95] Ultimately, "Rule 9 must be read in light of the basic pleading philosophy set forth in Rule 8…. This means that even those portions of Rule 9 that require specific or detailed allegations should not be construed strictly; it must be remembered that the federal rules contemplate a de-emphasis of the pleadings and a general simplicity in pleading practice."[96]

Here, Plaintiff's FAC offers ample particularity to meet the requirements of Rule 9(b). Plaintiff's FAC offers fourteen pages of specific and detailed allegations outlining Novartis' fraudulent behavior related to Beovu. A non-exhaustive sampling of those allegations includes:

(1) Allegations that Novartis authored and directed misleading publications in the medical literature that masked the true number of retinal vasculitis and retinal vascular occlusion cases seen in the clinical trials;[97]

(2) Allegations that Novartis omitted and concealed the true incidence rate and relative risk of retinal vasculitis and retinal vascular occlusion seen in its clinical trials in the labeling for the product; [98]

(3) Allegations that Novartis omitted a warning from its product labeling for Beovu until June 2020 despite having a wealth of knowledge supporting that label change well earlier in time and well before Plaintiff's use of Beovu and injury related thereto;[99]

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[95] *Id.*

[96] *Id.*

[97] Filing No. 30 ¶¶ 108, 109, 114-116, 133.

[98] *Id.* ¶¶ 110-113, 117-119, 133.

[99] *Id.* ¶ 120(b), 135.

(4) Allegations that Novartis encouraged ophthalmologists to switch patients from other similar therapies to Beovu while concealing that Novartis had not studied Beovu in patients that had previously used other similar therapies; and[100]

(5) Allegations that Novartis has continued to misrepresent and underreport the true relationship between Beovu and retinal vasculitis and retinal vascular occlusion in information disseminated to the public.[101]

Plaintiff's FAC also offers detail on the specific fraudulent representations relied on by Plaintiff and/or her prescribing physician.[102]

In sum, Plaintiff has offered very specific and detailed allegations concerning the various fraudulent behavior Novartis engaged in related to Beovu. These allegations well exceed the requirements of Rule 9(b) and thus dismissal of Plaintiff's fraudulent misrepresentation claim is unwarranted.

[100] *Id.* ¶120(c).

[101] *Id.* ¶¶ 121-130, 132, 134.

[102] *Id.* ¶¶ 120(a-c), 136, 137. Under Nebraska law, given the application of the learned intermediary doctrine, fraud claims in the context of a pharmaceutical case can be premised on fraudulent statements made to the plaintiff's prescribing physician. *See e.g., Kammerer v. Wyeth,* 2011 WL 5237754, *7 (D. Neb. Nov. 1, 2011) (applying Nebraska law and concluding that a question of fact existed as to the adequacy of the drug's label therefore precluding dismissal of claims premised on fraudulent statements and omissions made by manufacturer to plaintiff's physicians).

CONCLUSION

For the reasons stated herein, Novartis' Motion to Dismiss Plaintiff's First Amended Complaint should be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH NECivR 7.1(d)(3)

I HEREBY CERTIFY that the Plaintiff's Memorandum in Opposition to Defendant Novartis Pharmaceutical Corporation's Motion to Dismiss First Amended Complaint (Filing No. 33) complies with the type-volume limitations of NECivR 7.1(d)(3) because it contains 7,060 words. This count includes all text, including the caption, headings, footnotes, and quotations. I have relied upon Microsoft Office Home and Business word processing software used to prepare this Certificate of Compliance for the statement of word count.

/s/ Brandon L. Bogle
Brandon L. Bogle, Esquire